

PACKAGE LEAFLET: INFORMATION FOR THE USER

Bisoprolol 2.5 mg Film-coated Tablet

Bisoprolol 5 mg Film-coated Tablet

Bisoprolol 10 mg Film-coated Tablet

Bisoprolol fumarate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
 - If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet.

1. What Bisoprolol Tablets are and what they are used for.
2. What you need to know before you take Bisoprolol Tablets.
3. How to take Bisoprolol Tablets.
4. Possible side effects.
5. How to store Bisoprolol Tablets.
6. Contents of the pack and other information.

1. What Bisoprolol Tablets are and what they are used for

The active ingredient in this medicine is Bisoprolol fumarate. Bisoprolol Tablets belongs to group of medicines called beta-blockers. Beta-blockers protect the heart against too much activity.

Bisoprolol 2.5 mg, 5 mg and 10 mg Tablets are used in combination with other medicines to treat stable heart failure. Heart failure occurs when the heart muscle is too weak to pump blood around the circulation adequately. This results in breathlessness and swelling. Bisoprolol slows down the heart rate and makes the heart more efficient at pumping blood around the body.

Bisoprolol 5 mg and 10 mg tablets are also used to treat high blood pressure (Hypertension) and angina pectoris (Chest pain caused by blockages in the arteries that supply the heart muscle)

2. What you need to know before you take Bisoprolol Tablets

Do not take Bisoprolol Tablets if you:

- are allergic to Bisoprolol fumarate or any of the other ingredients of this medicine (listed in section 6).
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- have severe asthma or sever chronic lung disease.
- have severe blood circulation problem in your limbs (such as Raynaud's syndrome), which may cause your fingers and toes to tingle or turn pale or blue.

- have untreated phaeochromocytoma, a rare tumour of the adrenal gland (medulla).
- have metabolic acidosis, a condition when there is too much acid in the blood.
- have heart failure that suddenly becomes worse and / or that may require hospital treatment
- have a slow heart rate
- have very low blood pressure
- have a slow or irregular heart rate (less than 60 beats per minute). Ask your doctor if you are not sure

Warnings and precautions:

Talk to doctor before you start to take this medicine if you:

- have asthma or chronic lung disease
- have diabetes. Bisoprolol can hide the symptoms of low blood sugar
- are fasting from solid food
- are treated for hypersensitivity (allergic) reactions. Bisoprolol may make your allergy worse or more difficult to treat.
- have any heart problems
- have any liver or kidney problems
- have any problems with the circulation in your limbs
- are going to be given a general anaesthetic during an operation – tell your doctor that you are taking bisoprolol
- are taking verapamil or diltiazem, medicines used to treat heart conditions. Concomitant use is not recommended, see also “taking other medicines”
- have (or have had) psoriasis (a recurring skin rash)
- have phaeochromocytoma (a rare tumour of the adrenal gland). Your doctor will need to treat this before prescribing bisoprolol for you
- have a thyroid problem. The tablets can hide symptoms of an overactive thyroid.

Other medicines and Bisoprolol Tablets:

Tell your doctor if you are already taking or using any of the following as they may interact with your medicine:

- medicines for controlling the blood pressure or medicines for heart problems (such as amiodarone, amlodipine, clonidine, digitalis glycosides, diltiazem, disopyramide, felodipine, flecainide, lidocaine, methyldopa, moxonidine, , propafenone, quinidine, rilmenidine, verapamil)
- medicines for depression e.g. imipramine, amitriptyline, moclobemide
- medicines to treat mental illness e.g. phenothiazines such as levomepromazine
- medicines used for anaesthesia during an operation (see also “Take special care with Bisoprolol Tablets”)
- medicines used to treat epilepsy e.g. phenytoin and barbiturates such as phenobarbital
- certain pain killers (for instance acetyl salicylic acid, diclofenac, indomethacin, ibuprofen, naproxen)
- medicines for asthma or medicines used for a blocked nose
- medicines used for certain eye disorders such as glaucoma (increased pressure in the eye) or used to widen the pupil of the eye

- certain medicines to treat clinical shock (e. g. adrenaline, dobutamine, noradrenaline)
- mefloquine, a medicine for malaria
- all these drugs as well as bisoprolol may influence the blood pressure and/or heart function.
- rifampicin for the treatment of infections
- medicines to treat severe headaches or migraines (ergotamine derivatives).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines,.

Pregnancy and breast-feeding:

There is a risk that Bisoprolol Tablets can harm the baby if it is used during pregnancy. If you are pregnant, think you may be pregnant or are planning to become pregnant ask your doctor for advice before taking this medicine. He or she will determine whether you can take Bisoprolol Tablets during pregnancy. It is not known whether Bisoprolol fumarate passes in to breast milk. Therefore, breastfeeding is not recommended during treatment with Bisoprolol Tablets.

Driving and using machine:

The ability to drive or operate machinery may be affected, depending on how well you tolerate the medicine. Be especially careful at the beginning of the treatment, when the dose is increased or when the medication is changed, and when combined with alcohol.

<p>3. How to take Bisoprolol Tablets</p>

Always take this medicine exactly as your doctor has told you. Check with your doctor or your pharmacist if you are not sure. Treatment with Bisoprolol Tablets requires regular medical check up. This is particularly important in the initiation of therapy and during dose increase. Bisoprolol Tablets should be taken in the morning, with or without food. Swallow the tablet/s whole with some water and do not chew or crush them. The tablet can be divided into equal doses. Treatment with Bisoprolol Tablets is usually prolonged.

Adult:

Chest pain and high blood pressure:

Your doctor will start the treatment with lowest possible dose (5 mg). Your doctor will monitor you closely at the start of treatment. Your doctor will increase your dose to obtain the best possible dosage for you.

The maximum recommended dose is 20 mg once per day.

Patient with kidney disease:

Patient with severe kidney disease should not exceed 10 mg of bisoprolol once daily. Please consult your doctor before starting to use this medicine.

Patient with liver disease:

Patient with severe liver disease should not exceed 10 mg of bisoprolol once daily. Please consult your doctor before starting to use this medicine.

Heart failure:

Before you start using Bisoprolol Tablets, you should already be taking other medicines for heart failure including any ACE inhibitor, a diuretic and (as an added option) a cardiac glycoside.

Treatment with Bisoprolol Tablets must be started at a low dose and increased gradually. Your doctor will decide how to increase the dose, and this will normally be done in the following way:

- 1.25 mg bisoprolol fumarate once daily for a week
- 2.5 mg bisoprolol fumarate once daily for a week
- 3.75 mg bisoprolol fumarate once daily for a week
- 5 mg bisoprolol fumarate once daily for four weeks
- 7.5 mg bisoprolol fumarate once daily for four weeks
- 10 mg bisoprolol fumarate once daily for maintenance (on-going) therapy.

The maximum recommended daily dose of bisoprolol fumarate is 10 mg.

Depending on how well you tolerate the medicine, the doctor may also extend the time between dose increases. If your condition gets worse or if you no longer tolerate the drug, it may be necessary to lower the dose again or to stop treatment. For some patients a maintenance dose lower than 10 mg bisoprolol fumarate may be sufficient. Your doctor will tell you what to do. If you have to stop the treatment entirely, your doctor will usually advise you to reduce the dose gradually, as otherwise your condition may become worse.

Use in children:

Bisoprolol Tablets is not recommended for use in children.

Elderly patient:

In general adjustment of the dose is not needed. It is recommended to start with lowest possible dose.

If you notice that the bisoprolol dose is too strong or does not work well enough, please consult your doctor or pharmacist.

If you take more Bisoprolol Tablets than you should:

If you take too much medicine, or if a child has swallowed the medicine by mistake ask your doctor or hospital for assessing risk and advice. Take this leaflet and any tablets you still have with you. You may feel slow heartbeat, severe breathing difficulties, dizziness or tremor (due to decreased blood sugar).

If you forget to take Bisoprolol Tablets:

If you forget to take a dose, take it as soon as you remember it unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Bisoprolol Tablets:

Do not stop treatment suddenly or change the recommended dose without talking to your doctor first. If you need to stop treatment, it must be done gradually to avoid side effects.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects are important and will require immediate action if you experience them. You should stop taking Bisoprolol Tablets and see your doctor immediately if the following symptoms occur:

Common side effects (affecting fewer than 1 in 10 people):

- worsening of heart failure causing increased breathlessness and / or retention of fluid.

Frequency not stated:

- worsening of symptoms of blockage of the main blood vessels to the legs, especially at the start of treatment.

The following side-effects have also been reported:

Very common side effects (affecting more than 1 in 10 people):

- slow heart beat.

Common side effects (affecting fewer than 1 in 10 people):

- cold hands and/or feet
- numbness of hands and/or feet
- low blood pressure
- feeling sick, vomiting, diarrhoea, constipation
- tiredness*
- feeling weak
- dizziness*
- headache*.

Uncommon side effects (affecting fewer than 1 in 100 people):

- worsening of irregular heart beat
- sleep disorders
- depression
- breathing problems in patients with asthma or chronic lung disease
- muscle weakness, muscle cramps.

Rare side effects (affecting fewer than 1 in 1,000 people):

- changes in blood test results
- reduced tear flow (can be a problem if you wear contact lenses)
- hearing disorders
- blocked, runny nose

- inflammation of the liver (hepatitis) causing abdominal pain, loss of appetite and sometimes jaundice with yellowing of the whites of the eyes and skin and dark urine
- hypersensitivity reactions such as itching, redness and skin rash
- reduced sexual performance
- nightmares
- hallucinations (imagining things)
- fainting.

Very rare side effects (affecting fewer than 1 in 10,000 people):

- inflammation of the eye (conjunctivitis)
- aggravation of the skin condition psoriasis or the appearance of a similar dry, scaly rash
- hair loss.

* if treated for high blood pressure or angina then these symptoms occur especially at the beginning of treatment, or if your dosage changes. They are generally mild and often disappear within 1 to 2 weeks.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the the national reporting system (see contact details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

5. How to store Bisoprolol Tablets

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Bisoprolol Tablets contains:

The active substance is bisoprolol fumarate. Each tablet contains either 2.5mg, 5mg or 10mg Bisoprolol fumarate.

The other ingredients are Cellulose microcrystalline, Sodium starch glycolate (Type-A), Povidone K-30, Silica colloidal anhydrous, Magnesium stearate(E572), Hypromellose E-15(E464), Macrogol 400(E553), Titanium dioxide (E171), Talc.

What Bisoprolol Tablets looks like and contents of the pack:

For Bisoprolol 2.5 mg Tablets: White to off white, round, biconvex, film coated tablets, debossed 'b1' on one side and break line on other side

For Bisoprolol 5 mg Tablets: White to off white, round, biconvex, film coated tablets, debossed 'b2' on one side and break line on other side

For Bisoprolol 10 mg Tablets: White to off white, round, biconvex, film coated tablets, debossed 'b3' on one side and break line on other side

Pack sizes of 20, 28, 30, 50, 56, 60, 90 and 100 tablets per pack are registered for all strengths. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Accord Healthcare Limited, Sage house, 319 Pinner road, North Harrow, Middlesex HA1 4HF, United Kingdom

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